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Datasheet for the decision of 19 March 2026

Case Number: T 0122/25 - 3.2.01

Application Number: 13700569.0

Publication Number: 2806925

IPC: A61M5/315, A61M5/31

Language of the proceedings: EN

Title of invention:
INJECTION DEVICE WITH A SLIDING SCALE

Patent Proprietor:
Novo Nordisk A/S

Opponents:
1. Sanofi-Aventis Deutschland GmbH
2. medmix Switzerland AG

Headword:

Relevant legal provisions:
EPC Art. 123(2), 83, 84, 56

Keyword:
Amendments - extension beyond the content of the application as filed (no)
Sufficiency of disclosure - main request (yes) - undue burden (no)
Claims - clarity - main request (yes) - lack of clarity no ground for opposition - essential features - conciseness (yes) - functional features (yes)
Inventive step - main request (yes) - could-would approach

Decisions cited:
G 0001/03, G 0003/14, T 1484/18

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0122/25 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 19 March 2026

Appellant: (Patent Proprietor)	Novo Nordisk A/S Novo Allé 2880 Bagsværd (DK)
Representative:	Appelt, Christian W. Boehmert & Boehmert Anwaltspartnerschaft mbB Pettenkoferstrasse 22 80336 München (DE)
Appellant: (Opponent 1)	Sanofi-Aventis Deutschland GmbH Brüningstrasse 50 65929 Frankfurt am Main (DE)
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Party as of right: (Opponent 2)	medmix Switzerland AG Rütistrasse 7 9469 Haag (CH)
Representative:	Manitz Finsterwald Patent- und Rechtsanwaltspartnerschaft mbB Postfach 31 02 20 80102 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 22 November 2024 concerning maintenance of the European Patent No. 2806925 in amended fo rm.**

Composition of the Board:

Chairman	G. Pricolo
Members:	A. Wagner
	O. Loizou

Summary of Facts and Submissions

I. The appeals by the patent proprietor and the opponent 1 are directed against the decision of the opposition division to maintain European patent No. 2806925 in amended form on the basis of auxiliary request 1.

II. In its decision, the opposition division held among others that the main request filed on 31 July 2024 contravened Article 123(2) EPC while the requirements of Articles 83 and 84 EPC were met. Furthermore, the opposition division held that the objections raised under Article 56 EPC against auxiliary request 1 were not convincing.

III. In order to come to these conclusions the opposition division considered, among others, the following documents:

D1: US 2010/016877 A1
D2: EP 1819382 B1
D3: US 6,228,067 B1
D5: WO 2011/060785 A1
D7: WO 2008/148864
D10: US 6,899,699

IV. Oral proceedings by videoconference were held before the Board on 19 March 2026.

V. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request underlying the decision under appeal and a patent specification with amended paragraphs [0016] and [0031] filed with the letter of 25 July 2025 and the drawings as granted;

in the alternative that the patent be maintained on the basis of the main request underlying the decision under appeal with the description and drawings as granted, or in the alternative that the patent be maintained in amended form on the basis of one of the auxiliary requests 1 to 5.
All requests were filed with the patent proprietor's statement of grounds of appeal.

The appellant (opponent 1) requested that the decision under appeal be set aside and the patent be revoked as a whole.

The respondent and party as of right (opponent 2) did not submit any observations or requests and did not attend the oral proceedings as announced with letter dated 17 March 2026.

VI. Claim 1 of the main request with the feature numbering according to the impugned decision reads as follows:

1. An injection device for automatic spring driven injection of a liquid drug, comprising:

1.1 a dose setting mechanism by which doses of an individual size can be set by a user, and

1.2 a mechanical dose size display for displaying the size of the set dose,
which injection device further comprises:

1.3 a housing (2) defining an interior space and having a longitudinal window (3),

1.4 a rotatable dose dial button (10) coupled to the dose setting mechanism,

1.5 a rotatable scale drum (20) carrying indicia (22) for indicating the size of the set dose and

1.6 which scale drum (20) is functionally coupled to the dose dial button (10) to rotate when the dose dial button (10) is rotated to set a dose,

1.7 the rotatable scale drum (20) being rotatable within the interior space defined by the housing (2) during dose setting,

1.11 wherein the rotatable dose dial button (10) is axially retained in relation to the housing (2),
and
characterized in that

1.8 a sliding element (30) coupled to the scale drum (20), and provided with a window (35),

1.9 which sliding element (30) is adapted to slide axially in relation to the housing (2) during dose setting,

1.10 and through which window (35) the indicia (22) carried by the scale drum (20) is visible such that the longitudinal window (3) and the window (35) in combination with the indicia (22) form the dose size display,

1.12 wherein the sliding element (30) move axially within the boundaries of the housing (2) when the scale drum (20) is rotated,
characterized in that

1.14 neither the dose dial button (10) nor the scale drum (20) move axially and

1.15 the scale drum (20) stays within the boundaries of the housing.

VII. The appellant's (patent proprietor's) arguments relevant to the present decision may be summarized as follows:

Added subject-matter - main request

Claim 1 of the main request corresponded to claim 1 as originally filed with features 1.14 and 1.15 added. While the opposition division correctly held that features 1.14 and 1.15 found a literal basis on page 3, lines 25, 26 of the originally filed application, the opposition division erred that this passage was inextricably linked to the preceding bullet points on page 3. Besides, all features mentioned in the bullet points were already in the claim.

Sufficiency of disclosure

The findings of the opposition division were to be confirmed. In the main request, filed during an earlier appeal proceedings T1484/18, the problem with Article 83 EPC identified by the former Board was solved. With features 1.14 and 1.15 in claim 1, the skilled person understood that contradictory embodiments with a releasable coupling being any kind of a one-way ratchet mechanism as mentioned in paragraph [0016] of the patent no longer fell within the scope of claim 1.

Also feature 1 was sufficiently disclosed. The patent

provided in paragraphs [0017] and [0039] a general disclosure of the necessary components to put a spring driven injection into practice. This general concept was well known in the art (e.g. D2 or D10) and could be carried out by the skilled person without undue burden.

Clarity

The opposition division was right in holding that claim 1 of the main request satisfied Article 84 EPC.

Inventive step

The conclusion of the opposition division with regard to auxiliary request 1 that the subject-matter of claim 1 involved an inventive step applied likewise to the subject-matter of claim 1 of the main request and was to be confirmed. In particular the feature that both the dose dial button and the scale drum were axially retained was neither disclosed in nor rendered obvious by any of the cited prior art documents.

Adapted description

Paragraphs [0016] and [0031] of the patent specification were adapted to make very clear that the objection under Article 83 EPC identified in the earlier appeal proceedings T1484/18 was overcome.

VIII. The appellant's (opponent's) arguments relevant to the present decision may be summarised as follows:

Added subject-matter - main request

The finding of the opposition division that features

1.14 and 1.15 were taken out of the context of the description was correct. All features of the bullet points on page 3 preceding the lines 25 to 27 needed to be present in the claim. The claim wording was broader then what was disclosed in these bullet points. Further also the features of lines 29 to 31 of page 3 needed to be added to claim 1, contrary to the opposition division's findings.

Sufficiency of disclosure

In claim 1 of the main request, the option that the scale drum and the dose dial button were releasably coupled - such that the scale drum de-coupled from the dose dial button after dose setting when the scale drum rotates back - was not excluded. However, an exclusion was necessary according to T1484/18, because such a coupling was disclosed solely as a one-way ratchet mechanism (paragraph [0016] of the patent) and incompatible with feature 1.14. The claim was thus not sufficiently disclosed over the whole scope of the claim.

Furthermore feature 1 was directed to a device for spring driven injection. However, the patent in suit did not disclose any spring mechanism. The reference to D2 in paragraph [0039] of the patent in suit did not help because the claimed dose dial button and scale drum were incompatible with the spring driven dosing mechanism of D2 - contrary to the opposition division's opinion.

Clarity

Claim 1 was not clear for the following reasons:

- The term "*boundaries*" used in features 1.12 and 1.15 was unclear in particular as regards the wording in feature 1.14 "*within the interior space defined by the housing*".
- Features 1.14 and 1.11 were redundant such that claim 1 was not concise.
- Feature 1 as well as feature 1.14 could and should have been defined using structural features instead of functional features.
- Claim 1 failed to include all essential features. The "*sleeve 40 with a helical window 41*" was missing.

Inventive step

The findings of the opposition division were to be set aside.
Claim 1 did not provide an inventive step in view of the following combinations:
- D3 taken alone
- D10 with D5
- D2 taken alone
- D1 taken alone

In particular the distinguishing feature that the scale drum did not move axially in a device in which the dose dial does not move axially - or vice versa - had no technical effect and was an arbitrary design choice.

Adapted description

The amendments made to paragraphs [0016] and [0031] did not solve the problem of an insufficient disclosure.

Reasons for the Decision

1. **Added subject-matter - main request**

1.1 The main request meets the requirements of Article 123(2) EPC.

1.2 The originally filed application of the patent in suit is published as international application WO 2013/110538 A1. In the following reference is made to this document.

1.3 Claim 1 of the main request finds basis in original claim 1 for features 1 to 1.12 and page 3, lines 25 to 27 for features 1.14 and 1.15. It is noted that there is no feature identified as feature 1.13 in the claim (as it was replaced by features 1.14 and 1.15; see the last sentence of the paragraph after the "Feature Table" under section 2 of the reasons in the impugned decision).

1.4 The appellant (opponent 1) argued that line 25 on page 3 started with the word "*since*" which indicated that the information of the features of the preceding bullet points on page 3 were directly linked to features 1.14, 1.15. Therefore features 1.6, 1.11, 1.8 and 1.14 needed to be adapted according to the disclosure of the second (for feature 1.11), third (for feature 1.6) and last bullet point (for features 1.8, 1.14) - as held by the opposition division.

1.5 The Board is not convinced. Even if the Board agrees with the appellant (opponent 1) that lines 25 to 27 of page 3 indeed are related to the previous bullet points, all features mentioned in the bullet points on page 3 are already in claim 1 of the main request.

1.6 In the following, the features 1.6, 1.8, 1.11 and 1.14 of the main request are compared to the features 1.6', 1.8', 1.11' and 1.14' of auxiliary request 1 as maintained by the opposition division. Features 1.6', 1.8', 1.11' and 1.14' were amended to correspond to the wording of the bullet points. The amendments are indicated with strikethrough and underlining.

1.6.1 Feature 1.6 versus feature 1.6'

Feature 1.6 was amended as follows:

1.6' which scale drum (20) is functionally coupled to the dose dial button (10) such that the scale drum follows rotation of the dose dial button ~~to rotate~~ when the dose dial button (10) is rotated to set a dose,

(a) The appellant (opponent 1) argued that the wording "*follows rotation*" in feature 1.6' implied that both parts rotated in the same direction with the same speed. Feature 1.6 was not limited thereto and therefore broader in scope than originally disclosed.

(b) The Board does not agree. The technical information of the wording of 1.6 and of 1.6' is the same. In both cases the feature defines that the rotation of the dose dial button causes the rotatable scale drum to rotate. The original wording in features 1.6 was always meant, disclosed and understood by the skilled person as rotating the scale drum in the same direction as the dose dial button. Furthermore, neither feature 1.6 nor feature 1.6' contains any information regarding the speed ratio between the scale drum and the dose dial button.

(c) The appellant (opponent 1) also objected that the term "*functionally coupled*" in feature 1.6 was broader than the term "*coupled*" in the third bullet point on page 3.

(d) The Board however confirms the opposition division's findings (impugned decision, point 9.3) that the term "*functionally coupled*" in feature 1.6 was already present in the claim as originally filed. In the given context of the claim, the term "*coupled*" is not more restrictive than "*functionally coupled*".

1.6.2 Feature 1.8 versus feature 1.8'

The following amendments were made to feature 1.8:

1.8' a sliding element (30) coupled to the scale drum (20) such that the sliding element moves axially when the scale drum is rotated, and provided with a window,

(a) The appellant (opponent 1) argued that the expression "*such that*" specified that due to the coupling the axial movement occurs. In feature 1.8, this cause for the axial movement was missing.

(b) The Board does not agree. From feature 1.8 seen together with feature 1.12 ("*the sliding element move axially [...] when the scale drum is rotated*") the skilled person unambiguously understands that it is the coupling between the sliding element and the scale drum that causes the axial movement of the sliding element.

1.6.3 Feature 1.11 versus 1.11'

The following amendments were made to feature 1.11:

1.11' wherein the rotatable dose dial button (10) is axially retained in relation to the housing (2) such that dose dial button is limited to rotational movement,

(a) The appellant (opponent 1) argued that feature 1.11' limited the possible movement for the dose dial button to a rotation while original feature 1.11 only excluded axial movement such that a swivelling or a lateral movement still was encompassed.

(b) The Board is not convinced. The limitation to rotational movement is already included in feature 1.11 of the main request defining that the dose dial button is rotatable but axially retained. The original wording in feature 1.11 was always disclosed and understood by the skilled person in the sense that the only degree of freedom for the dose dial button is a rotational movement. The description is silent about, and also the figures do not suggest, any other degree of freedom. The expression "*such that*" in feature 1.11' only emphasised that the sole remaining degree of freedom for the dose dial button is the rotation.

1.6.4 Feature 1.14 versus feature 1.14'

Feature 1.14 was amended as follows:

1.14' neither the dose dial button (10) nor the scale drum (20) move axially, the movement of the rotatable scale drum is limited to rotation within the interior space defined by the housing during dose setting

(a) As for feature 1.11, the appellant (opponent 1) argued that the exclusion of an axial movement in feature 1.14 was broader than the limitation to a rotation in feature 1.14'.

(b) The Board sees the added feature already included in claim 1 of the main request with features 1.7 and 1.14.
As for feature 1.11, the original wording in feature 1.14 was always disclosed and understood by the skilled person in the sense that the only remaining degree of freedom for the scale drum is a rotation - as is also apparent from the description and the figures.

1.7 Hence, claim 1 of the main request does not add any new technical information compared to the information in the bullet point on page 3 of the description as originally filed.

1.8 **Further objection under Article 123(2) EPC**

1.8.1 The appellant (opponent 1) argued that also the features of page 3, lines 29 to 31 needed to be added to claim 1 as these features likewise were inextricably linked to the precedent bullet points on page 3.

1.8.2 Lines 29 to 31 recite: "*Further, as the sliding element is limited to axial movement within the parameters of the housing and no parts grow out of the housing a larger part of the scale drum can be utilized for carrying indicia as the sliding element can move along the entire scale drum.*"

1.8.3 The Board agrees with the opposition division (impugned decision, point 9.3, last paragraph) that the relevant features in lines 29 to 31 are already reflected in claim 1. The appellant (opponent 1) did not submit any argument why the findings of the opposition division were not correct. The Board therefore does not see any reason to deviate from the opposition division's conclusion regarding this issue.

2. Article 83 EPC

2.1 The Board confirms the opposition division's findings that the main request satisfies the requirements of Article 83 EPC (impugned decision, point 3).

2.2 **Objection A:**
Feature 1.14 combined with paragraphs [0016], [0031] of the patent specification

2.2.1 The appellant (opponent 1) argued that the patent in suit failed to disclose an embodiment in which the dose dial button and the scale drum were axially retained AND the coupling between these two parts was made through a releasable coupling such that when the set dose is injected, the dial button did not rotate back with the scale drum - as described in paragraphs [0016] or [0031] of the patent in suit.

As held in T1484/18 concerning the same patent, it was held that a releasable coupling - previously a feature of the claim and only specified in the patent as a one-way ratchet mechanism - was not compatible with feature 1.14. Undisputedly, in a one-way ratchet mechanism, at least one of the cooperating components had to be axially moved to get disengaged from the other component of the one-way ratchet. Such an axial

movement was however excluded by feature 1.14.

Claim 1 of the main request still encompassed embodiments with the dose dial button and the scale drum being releasably coupled although both were axially fixed. The de-coupling option was within the technically reasonable claim interpretation and presented as the preferred embodiment. However the patent did not provide any enabling disclosure how this could be put in practice together with feature 1.14. Thus, the invention was still not sufficiently disclosed over the whole scope of the claim.

Contrary to the opposition division's opinion, the skilled person would not disregard a "releasable coupling" as a non-working embodiment. To do so, G 0001/03 (reasons point 2.5.2) made clear that such an approach was only to be applied in cases where the patent disclosed a large number of alternatives and the patent contained sufficient information for finding appropriate alternatives over the claimed range. None of these conditions were met in the present case. Therefore, in accordance to G 0001/03, claim 1 required a disclaimer for a releasable coupling between the dose dial button and the scale drum.

2.2.2 The Board is not convinced.

It is true that a releasable coupling - being only disclosed as a kind of one-way ratchet mechanism (paragraph [0016]) - is not compatible with the dose dial button and the scale drum not being axially movable (feature 1.14). Nevertheless, the Board agrees with the opposition division that a disclaimer to exclude the option of a releasable coupling in claim 1 according to G 0001/03 is not applicable, in particular

because embodiments with a releasable coupling in the sense of paragraph [0016] of the patent specification do not fall under the scope of claim 1 - contrary to the appellant's (opponent's) opinion.

According to established case law of the Boards of Appeal, the skilled person reads the patent with the aim of making technical sense out of the disclosure as a whole. When doing so, the skilled person unambiguously understands that embodiments of claim 1 and embodiments as disclosed in paragraphs [0016] and [0031] of the patent in suit exclude each other. The specification as a whole only teaches a releasable coupling as a kind of one-way ratchet such that only the scale drum rotates back after a dose is set. The releasable coupling is not presented for any other purpose or in any other way. The skilled person does not consider a releasable coupling as falling under the claimed subject-matter, as the only possible embodiment with a releasable coupling is in contradiction with feature 1.14.

It is further noted that the patent does not present the releasable coupling as the preferred embodiment as suggested by the appellant (opponent 1). Paragraph [0016] ("*in one embodiment this coupling can be made such that*") as well as paragraph [0031] ("*The connection between the dial button 10 and the scale drum 20 can be made through a releasable coupling*") present the releasable coupling as an equivalent alternative to a non-releasable coupling with which the dose dial button and the scale drum both rotate back after the dose is set.

2.3 **Objection B:**
The automatic spring driven injection of feature 1

2.3.1 The appellant (opponent 1) argued that the claim was directed to a device for automatic spring driven injection (feature 1) but the patent did not disclose any possible way to reproduce an automatic spring driven injection in combination with features 1.1 to 1.15. All references in the patent to a spring driven injection (e.g. in D2 or D10) were incompatible with the claimed subject-matter and could not provide an enabling disclosure, in particular because feature 1.14 was not realized in any of these references.

Contrary to the opposition division's findings, the reference to D2 in paragraph [0039] of the patent did not provide an enabling disclosure. The implementation of the spring mechanism of D2 would not be possible or at least required significant modifications going beyond the common general knowledge of the skilled person.
Also paragraph [0017] referred to by the opposition division did not explain how a torsion spring was implemented in the claimed device such as to result in an automatic spring driven injection device.

2.3.2 The Board is not convinced and confirms the opposition division's findings. In particular the reference to D2 in paragraph [0039] and the mentioning of the torsion spring in paragraph [0017] in the patent in suit enables the skilled person to put feature 1 in combination with features 1.1 to 1.15 into practice.

Paragraph [0017] discloses that "*The injection device is preferably of the kind in which a torsion spring is*

strained during dose setting such that a torque is build up in the torsion spring."

Paragraph [0039] discloses that "*The interior of the scale drum 20 is preferably occupied by a spring driven dosing mechanism as e.g. disclosed in EP 1,819,382 [i.e. D2].*"
D2 discloses an injection device as mentioned in paragraph [0017] with a torsion spring.

Thus, the skilled person gets the teaching to use the spring driven injection mechanism of D2 for feature 1 and to replace the known dose setting mechanism of D2 by a device with features 1.1 to 1.15.

Contrary to the appellant's (opponent 1's) opinion, the spring driven injection mechanism of D2 is compatible with the dose setting mechanism of the patent in suit without requiring extensive modification.

The spring driven injection mechanism of D2 comprises inter alia the torsion spring 12, the piston rod 2 and the drive member 6 as described in paragraphs [0024] and [0029] and shown in figure 1 to 3 of D2 (figures 1 and 3 partly reproduced below, left hand side).
The injection mechanism of D2 with the torsion spring 12 does not need any axial displacement to be tensioned for the ejection of the liquid drug. This is also described in D2, paragraph [0006].

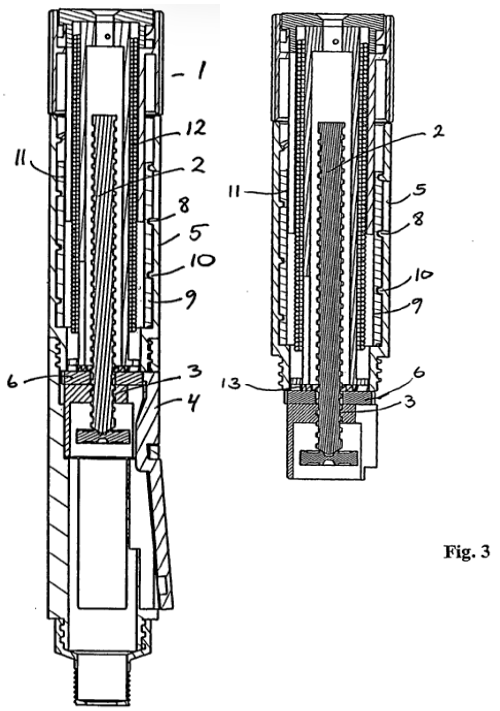


Fig. 1

Fig. 3

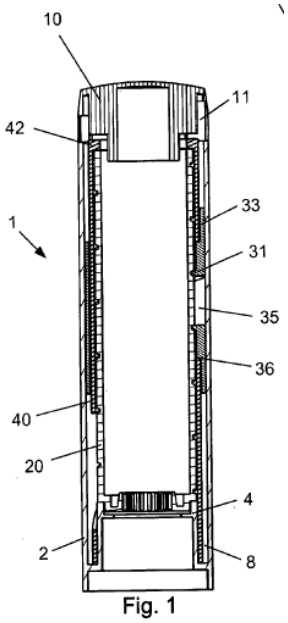


Fig. 1

Paragraph [0017] of D2 discloses that the torsion spring 12 can be arranged between the housing and the dose setting member 1 such that when the dose setting member is rotated the torsion spring is strained. The dose setting member 1 in D2 corresponds to the dose dial button 10 in the patent in suit. In both disclosures, the dose dial button does not move axially. Therefore, when implementing the spring mechanism of D2 - as proposed in paragraph [0039] of the patent in suit - into the device of the patent in suit (see e.g. figure 1 reproduced above, right hand side), the skilled person understands that the torsion spring can be attached in the same way as in D2 between the housing and the rotatable dose dial button. That in D2 the scale drum moves axially is not of any relevance.

Consequently, a skilled person readily understands, on the basis of the information contained in the patent specification as a whole, how the spring driven

injection mechanism of D2 is to be incorporated into the claimed device. Feature 1 can thus be carried out by the skilled person without undue burden.

3. Article 84 EPC

3.1 The Board confirms the opposition division's findings that the main request satisfies Article 84 EPC (impugned decision, point 4).

3.2 With regard to the objections raised under Article 84 EPC, the parties referred during oral proceedings to the arguments provided in writing and did not make any further submission. The written arguments were already taken into account in the Board's communication pursuant to Article 15(1) RPBA; the respective findings set out therein are hereby confirmed as follows.

3.3 "within the boundaries of the housing" in feature 1.12, 1.15

3.3.1 The appellant (opponent 1) objected that no definition for the term "*boundaries*" used in features 1.12 and 1.15 was given. The term was unclear. Furthermore the term "boundaries" was not clear seen together with added feature 1.14, introducing the term "*within the interior space defined by the housing*". It was unclear what the difference between these two definitions might be.

3.3.2 However, the alleged unclarity of the term "*boundaries*" is not caused by the amendments made to claim 1 but was already in claim 1 as granted (feature 1.12). The same applies to the term "*boundaries*" versus the term "*interior space*". In claim 1 as granted, both terms are already used (features 1.3 and 1.12). As Article 84 is

not a ground for opposition (G 0003/14), this objection is not valid.

3.4 Features 1.14 and 1.11 not concise (impugned decision, point 4.2)

3.4.1 According to the appellant (opponent 1), feature 1.11 already defined that the dose dial button "is axially retained". Feature 1.14 defining that the dose dial button does not move axially did not add anything. Claim 1 was thus not concise.

3.4.2 The Board agrees with the opposition division and the patent proprietor that features 1.11 and 1.14 are different. Feature 1.14 is in the characterising portion and defines a difference over the prior art. While in the prior art a dose dial button which is axially retained was considered as being known, (feature 1.11), a device with a dose dial button and a scale drum being axially retained was considered not known. Feature 1.14 emphasizes, in addition to feature 1.11, that both elements do not move axially.

3.5 Feature 1.14: unduly broad functional feature (decision, point 4.2)

3.5.1 The appellant (opponent 1) argued that feature 1.14 could and should have been defined using structural features instead of functional features. Furthermore feature 1.14 contradicted paragraph [0039] in which reference was made to D2 with an axially moving dial button.

3.5.2 The Board agrees with the opposition division that feature 1.14 defines a result to be achieved, however the result is one which can be directly and positively

verified by known measures to the person skilled in the art. Feature 1.14 is thus clear. That in D2 the dose dial button does not meet feature 1.14 is of no relevance for Article 84 EPC.

3.6 Feature 1: broad functional definition

3.6.1 In the appellant's (opponent 1's) view the function "*for automatic spring driven injection*" could have been defined by structural features. Claim 1 did not define any structural feature directed to the injection but defined only features for the dose setting operation.

3.6.2 Irrespective of the fact that feature 1 was already in claim 1 as granted (G 0003/14), the Board agrees with the appellant (patent proprietor) that here a functional feature is allowable as it can easily be verified by the person skilled in the art.

3.7 Essential feature "sleeve with a helical window" missing

3.7.1 According to the appellant (opponent 1) the sleeve 40 that shields the not selected ciphers was essential in order not to confuse a user by displaying several different dose values. The sleeve was also essential to solve the problem posed. Only because of the sleeve, the sliding element could remain short and kept within the boundaries of the housing.

3.7.2 Regardless of the question of the admissibility of this objection submitted for the first time in appeal, the objection can not convince.
Firstly, it was not submitted why this alleged clarity issue was caused by the amendments made to claim 1 as granted (G 0003/14). Secondly, the device can function

properly without the sleeve. Even if the not selected ciphers are not shielded, the selected dose is still displayed in the window 35 of the slider element.

3.8 The requirements of Article 84 EPC are thus met.

4. Inventive step

4.1 The opposition division held with regard to auxiliary request 1 that the claimed subject-matter was not rendered obvious by the cited prior art.
As the reasoning likewise applies to the main request, the Board confirms the opposition division's findings.

4.2 In the following, the feature numbering 1.14a and 1.14b as used by the appellant (opponent 1) is used:

1.14a the dose dial button does not moves axially
1.14b the scale drum does not move axially

4.3 As in opposition proceedings (impugned decision, point 12), the attacks starting from D10 combined with D5, or starting from D3, D1 or D2 seen alone were submitted. None of the attacks could convince the Board for the following reasons.

4.4 D10 as closest prior art combined with D5

4.4.1 In D10, reference is made to figures 1A and 2A (see below) and to column 6, lines 5 to 9 and line 52 to column 7, line 11, and column 8, lines 21 to 55.

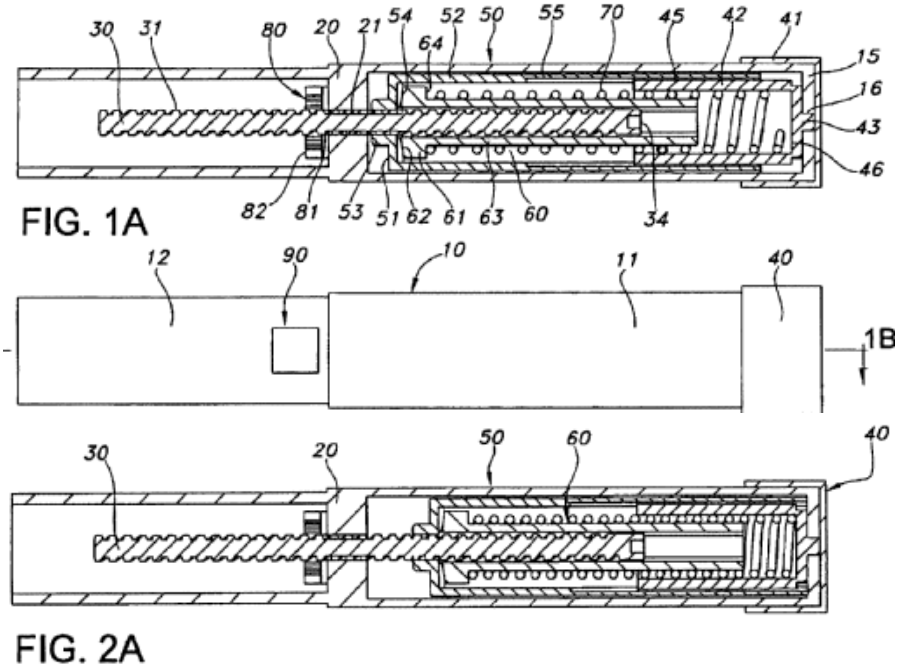


FIG. 1A

FIG. 2A

4.4.2 The device of D10 is for spring driven injection (column 2, lines 51, 52). The housing 10 has a window 17 (figure 4) and comprises in its first portion 11 a dose setting mechanism. The dose dial button is seen in the dose setting knob 40. The scale drum is seen in the dose setting member 50 provided inside the housing. On the skirt 52 of the scale drum 50, numbers are printed that can be inspected through the window 17. The scale drum 50 is functionally coupled to the dial button 40 by a groove 55/tongue 45 connection. When setting a dose, the dose dial button is rotated but does not move axially. The scale drum 52 rotates with the dose dial button 40 and moves axially in the housing via a threaded connection 53 at the plunger 30. The axial displacement becomes apparent when comparing the position of the drum 50 in figure 1A and 2A.

4.4.3 Claim 1 undisputedly differs from the device of D2 at least in features 1.8 to 1.10, 1.12 (sliding element) and feature 1.14b (axially retained scale drum).

4.4.4 The appellant (opponent 1) argued that claim 1 comprised an aggregation of features.

(a) The sliding element as one distinguishing feature solved the problem to allow the size of the indicia to be increased. An obvious solution to this problem was provided in D5.

D5 dealt with the same problem (page 7, lines 1 to 7 "*make the numbers bigger*") as the patent in suit (page 2, lines 27, 28 "*device in which the size of the individual ciphers [...] can be increased*"). The second embodiment of D5 (figures 8 to 10, see below) comprised an axially moving sliding element ("*sliding window 19*") coupled to the rotatable scale drum 5. To fit the sliding element 19, the housing had an elongated hole (page 15, lines 6 to 17).

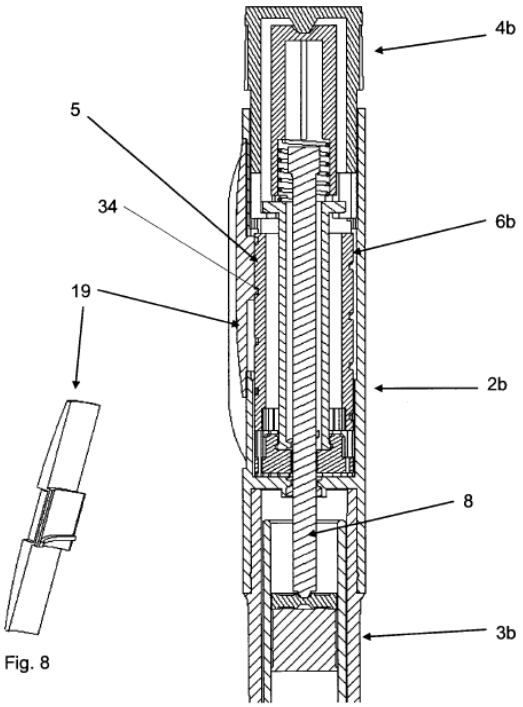


Fig. 8

Fig. 9

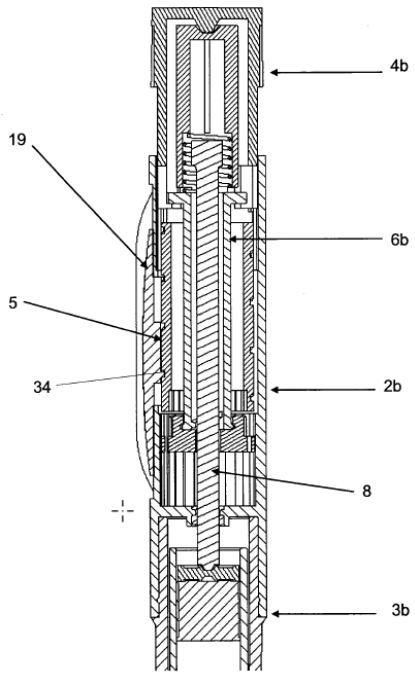


Fig. 10

D5 also gave instructions how to implement the sliding window 19 by comparing the second and the first embodiment of D5. It only required to enlarge the small window in the housing of the first embodiment (figure 1) and to provide the outer thread 34 at the scale drum 5.

The skilled person would have applied these straight forward measures with the instructions given in D5 to the device of D10.

(b) The axially retained scale drum as the other distinguishing feature was independent therefrom, did not contribute to the claimed function and could thus be disregarded.
Alternatively, scale drums being axially retained were well known as obvious alternatives and a mere arbitrary design choice without any technical effect, see e.g. D1 (paragraphs [0050, 0051]), D3 (figure 20) or D7 (paragraph bridging pages 10/11).

4.4.5 The Board is not convinced. Even if the provision of a sliding element - as a partial problem - might be rendered obvious by the combination of D10+D5, this combination would result in an axially moving scale drum because in D10 as well as in D5, the scale drum moves axially (see D5, page 15, lines 14, 15 and compare scale drum 5 in figures 9 and 10). The combination would result in an alternative to the claimed solution.

(a) Contrary to the appellant's (opponent l's) opinion, the feature that the scale drum is axially retained (feature 1.14b) can not be ignored in a proper problem-solution approach. As pointed out by the patent proprietor, it is the interrelationship

between all distinguishing features that results in the claimed solution.

(b) The argument that the axially retained scale drum was merely an obvious alternative can likewise not convince. There is no motivation for the skilled person to additionally provide, in a modified device that might result from the combination of D10 and D5, an axially retained scale drum as a simple design option.

As brought forward by the patent proprietor, in D10 the axial movement of the scale drum has the essential function of tensioning the spring for the spring driven ejection of the liquid drug (see D10, column 8, lines 35 to 43). Without this axial movement, further modifications would become necessary to guarantee proper functioning of the device.
Also in D5, the movement of the scale drum is inextricably linked to the injection after the dose setting (see D5, page 1, lines 6, 7 and page 4, lines 12 to 18).

Furthermore, when considering known axially fixed scale drums as e.g. shown in D1 (figure 29) or D3 (figure 13), either the dose dial button moves axially (D1) or no separate dose dial button is provided (D3). D7 discloses a very different two part scale drum E, Z which can not be seen as a generally known alternative.

4.4.6 Finally, the appellant (opponent 1) was of the opinion that the opposition division's perspectives for assessing the requirements of Article 83 EPC and the requirements of Article 56 EPC were extremely

unbalanced. On the one hand, the skilled person had the skills to put feature 1 into practice although the patent in suit did not disclose at all how a spring driven injection might work (see point 2.3 above). Onthe other hand, the skilled person was not able to maintain the functionality of the spring driven injection in D10 when providing the mere alternative of an axially restrained scale drum.

4.4.7 The Board does not agree. As explained above, the patent specification as a whole gives sufficient information to enable the skilled person to put the invention into practice without undue burden.
For inventive step, the question is not whether the skilled person could maintain the functionality of the spring driven injection when providing an axially restrained scale drum together with an axially restrained dose dial button. The question is whether the skilled person would be prompted to modify the prior art in an obvious manner to arrive at the claimed subject-matter without becoming inventive. In the present case, there is no hint or motivation for the skilled person to do so.

4.4.8 Consequently, the feature combination 1.14a with 1.14b involves an inventive step over D10 combined with D5 as nowhere in the cited prior art the dose dial button AND the scale drum are axially restrained.

The questions raised by the patent proprietor whether claim 1 differs from D10 in further features, e.g. feature 1.3, or whether a sliding element in the form of a sliding window 19 as shown in figure 9 of D5 was to be considered as being "*within the boundaries of the housing*" as required by feature 1.12, were thus not decisive.

4.5 D3 as closest prior art taken alone

4.5.1 The injection device of D3 (see figures 13, 20, 21, reproduced below) has a housing 110 comprising a tubular distal section 112 with a longitudinal window 230 and a tubular proximal section 116. The part of the proximal housing section 116 that extends into the distal housing section 112 functions as scale drum ("*distal section 117*"). The proximal housing section 116 as a whole rotates but does not move axially. The device further comprises an axially moving sliding element 154 that is coupled to the scale drum part 117 and is provided with a window 232 (column 2, lines 34 to 38, column 3, lines 23 to 32).

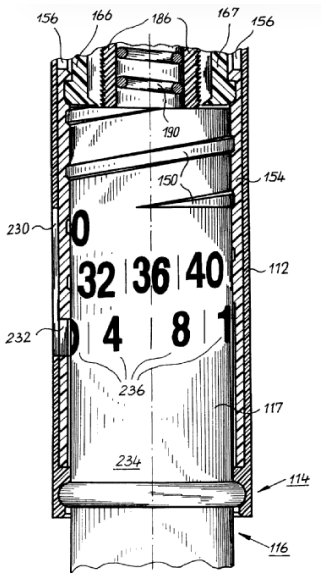


Fig. 20

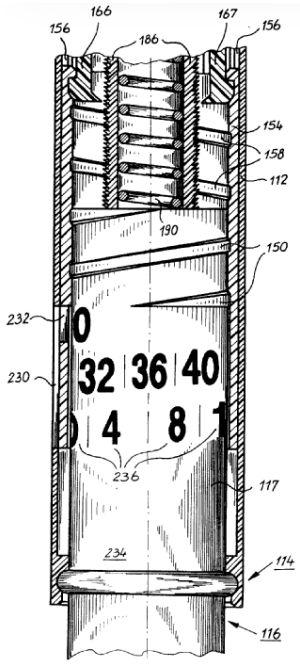


Fig. 21

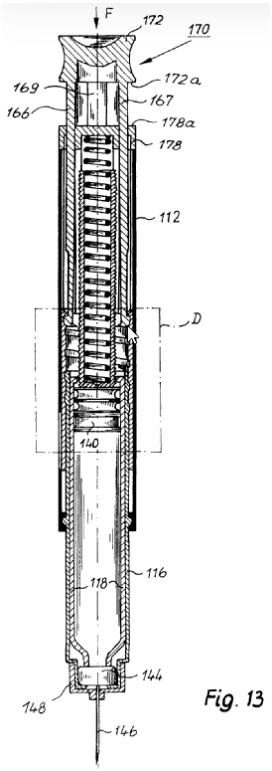


Fig. 13

To set a dose, the tubular section 116 of the housing with the integral scale drum 117 is rotated relative to the distal housing section 112 what in turn moves the sliding element 154 axially (column 6, line 52 to column 7, line 9). It is noted that the part 170 in

figure 13 is not a dose dial button but the actuating member that is to be pushed down to set the dose.

4.5.2 Claim 1 differs from D3 at least in feature 1 and in features 1.4, 1.6.

(a) The appellant (opponent 1) was of the opinion that claim 1 left open what was meant with "*spring driven injection*". The compression spring 190 in D3 drove the piston rod ("*expressing member 186*") into abutment with the plunger 140 (column 5, lines 51 to 59). This fell under the broad wording of feature 1.

The Board does not agree. As brought forward by the patent proprietor, D3, column 4, lines 26, 27 explicitly discloses that the function of the spring "*is not, as one might perhaps believe, the support of the injection process*". The injection occurs purely manually by pressing down the actuating member 172 as described in column 5, lines 1 to 20. Feature 1 is thus not disclosed.

(b) With regard to feature 1.4, the appellant (opponent 1) argued that the dose dial button was only defined by its function. The term "*button*" was broad and could simply mean "element". In D3, the proximal housing 116 constituted the dose dial button, the section 117 inside the distal housing 112 constituted the scale drum. Neither the claim nor the description of the patent in suit contained a definition which would contradict the interpretation of the tubular housing section 116 to be seen as a "*button*". The function of the section 116 was identical to the function of the dose dial button in claim 1.

The Board is not convinced. Even if the function of the tubular housing section 116 is comparable to that of the claimed button, it does not have the consequence that the housing section 116 is a "*button*". Without defining what exactly constitutes a "*button*", it is noted that, by normal acceptance, a longitudinal tubular housing designed to receive an elongated cartridge with injectable fluid is not what a skilled person would regard as a "*button*". This understanding is also supported by the figures of the patent. Hence, D3 does not disclose feature 1.4.

(c) Regarding feature 1.6, it was argued that the expression "*functionally coupled*" included "permanently coupled" or "integral". Nothing else was disclosed in D3 wherein the scale drum 117 was integral and therewith permanently coupled with the dose dial button 116. The expression "*functionally coupled*" did not require two separate parts. Again, the functioning of the dose setting mechanism in D3 was identical to what was claimed.

The Board does not agree. As brought forward by the patent proprietor, it is clear from the wording of the claim that a "*button*" (feature 1.4) and a "*drum*" (feature 1.5) must be two different parts. Furthermore, to couple the button and the drum, it requires coupling means. Even if the claim is broad about this feature, a single-piece tube 116, 117 as disclosed in D3 does not comprise any coupling means. Feature 1.6 is thus not disclosed.

(d) In an alternative argumentation, the appellant (opponent 1) considered the needle carrier 148

(figure 13, column 2, lines 43 to 46) that is threaded on the section 122 of the housing section 116 as a respective "*button*". The needle carrier and the tubular section 116 were functionally coupled in the sense of feature 1.6. The user could rotate the needle carrier to set the dose in the same way as described for the housing section 116.

Even if the Board may follow the view that the term "*button*" was applicable for the needle carrier, the Board is not convinced that the needle carrier is suitable as a dose dial button. To set a dose, the button needs to be rotatable in both directions (for increasing or decreasing the dose). However, in one of the directions, the needle carrier 148 would come loose from the threaded section 122 and would not serve to adjust the dose any more.

4.5.3 With the distinguishing features 1, 1.4 and 1.6, the Board agrees with the appellant (opponent 1) that feature 1 on the one hand and features 1.4, 1.6 on the other hand solve different partial problems. However, contrary to the appellant's (opponent 1's) view, both group of features are not rendered obvious by D3.

Feature 1

4.5.4 According to the appellant (opponent 1), feature 1 was broad and fell within the common general knowledge of the skilled person. The skilled person was motivated by D3 itself to implement feature 1. D3, column 7, lines 34 to 38, provided the hint to design the device as a "*full automatic*" injector.

The skilled person would simply make spring 190 in D3 stronger such that after setting the dose, the

injection was spring driven. The implementation of feature 1 did not involve an inventive step - in particular as according to the findings with regard to sufficiency of disclosure, the skilled person was able to put feature 1 into practice although the patent in suit did not give any information thereon. When assessing Article 56 EPC, the skilled person should be equipped with the same skills as when assessing Article 83 EPC. The skilled person would thus be aware of the steps required to make the device of D3 suitable for a spring driven injection.

4.5.5 The Board is not convinced. When starting from the embodiment of D3 as shown e.g. in figures 13, 20 and 21, it is not obvious to implement therein a spring driven injection.

In D3, after the dose is set, the user has to pull on actuating member 172 to bring the device in the injection-ready position in which the expressing element 186 is brought in abutment with the plunger 140 under the action of the spring 190 (see figures 7 to 10, column 5, lines 45 to 57). For the injection, the user then presses on the actuating member 172 to inject the selected dose (column 6, lines 3 to 10, figures 11, 12).

As argued by the patent proprietor, the spring 190 in figures 13, 20 and 21 can not easily be used to drive the injection. Should the spring be made stronger, then the injection would immediately be initiated as soon as the device reaches the injection-ready position (figure 10). The moment of injection could not be determined by the user. Such a behaviour would not be acceptable for a device used to self-inject e.g. insulin (D3, column 1, lines 16 to 20, column 2, line 59).

Even if the Board can agree that D3, column 7, lines 34 to 38 includes a hint to consider an automatic spring driven injection, it is not obvious how this function is to be implemented in the embodiment of figure 13. Such a modification would not only require the provision of a second spring, that is to be tensioned during dose setting but also the provision of a user-operable release mechanism - as argued by the patent proprietor. Contrary to the appellant's (opponent 1's) opinion, such modifications are not obvious when starting from a specific, full functional device in which all components interact with each other and are adapted to be as simple and as foolproof as possible.

In the context of this assessment of inventive step, there is also no difference in skills as compared to the assessment of the requirements of Article 83 EPC with regard to feature 1 for the patent in suit. As explained in point 2.3 above, the patent in suit explicitly refers in paragraphs [0017] and [0039] to a spring driven injection mechanism that is compatible with the claimed device. The skilled person gets all information at hand, while in D3 no details are given about feature 1.

Features 1.4, 1.6

4.5.6 The appellant (opponent 1) provided several lines of attack:

1. Should the claim be understood as requiring two separate parts for the scale drum and the dose dial button, it was concluded that this differentiating feature was devoid of any technical effect. In the patent in suit, the two parts behave as if they were a

single part. Providing two parts was thus an arbitrary non-functional modification.

2. Assuming a technical contribution, the following was argued:

(a) The underlying technical problem could be formulated based on the different functions of the housing sections 116 and 117. While for the scale drum part 117 a good readability of the indicia was required, the cartridge receiving section 116 required a check of the cartridge's fill level. The problem to be solved was to optimize the components parts regarding their individual requirements.

(b) Another problem to be solved could be seen in facilitating reusing the device and replacing an empty cartridge.

(c) It might also be an object to facilitate production and assembly of the component part.

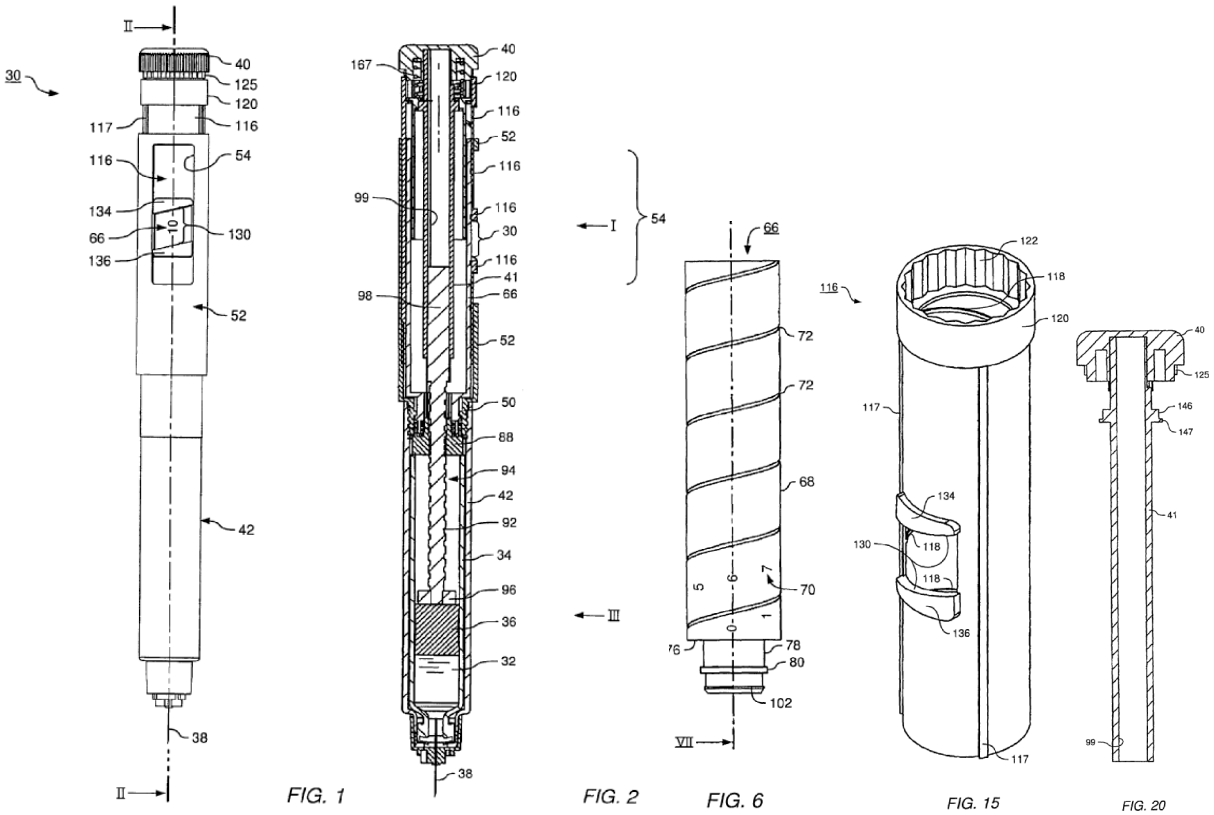
All these technical problems would obviously be solved by the skilled person by providing two separate parts. The two parts would then be functionally coupled such that the dose dial button part 116 and the scale drum part 117 behave as one part as already disclosed in D3.

4.5.7 The Board is not convinced because even if the skilled person would consider two parts for the two housing sections 116 and 117, the proximal tubular housing section that receives the cartridge still is not designed as a button (see point 4.5.2 b) above).

4.6 D3 alone can thus not render obvious the claimed subject-matter.

4.7 D1 as closest prior art taken alone

4.7.1 The injection device of D1 is best shown in figures 1, 2, 6, 15, 20 (see below) and described in paragraphs [0045], [0051], [0052], [0060] and [0072].
The device comprises a housing 52 with a longitudinal window 54, a dose dial button ("*rotary knob 40*"), a rotatable but axially retained scale drum ("*metering element 66*") and a sliding element ("*injection sleeve 116*") with a window 130. The dose dial button 40, that it rotated to set a dose, moves axially together with the rotatably coupled sliding element 116 during dose setting (paragraph [0072], see figure 29, reproduced below, point 4.6.3).



4.7.2 It is undisputed that claim 1 at least differs from the device of D1 in feature 1 (spring driven injection) and

features 1.11, 1.14a (axially retained dose dial button).

4.7.3 Features 1.11, 1.14a involve an inventive step when starting from D1.

(a) In the appellant's (opponent l's) view, features 1.11, 1.14a did not contribute to the solution of the problem of larger ciphers (patent in suit, paragraph [0007]). This became apparent from D1, paragraph [0075], according to which large ciphers could be provided without an axially retained dose dial button.

The Board does not agree. It might be that larger ciphers are possible with an axially moving dose dial button. However, in an injection device, all structural features interact with each other and influence each other as will be explained for D1 in sub-point c) below. Thus, in an alternative solution that provides larger ciphers with an axially retained dose dial button, all structural features have to be considered and seen together.

(b) Alternatively, the appellant (opponent 1) argued that the provision of an axially retained dose dial button was an obvious measure well known in the art, see e.g. D7 or D2.

However, even if it might be that axially retained dial buttons are known, it is noted that then - as shown in D7 and D2 - the scale drum moves axially. Providing an axially retained dial button when the scale drum is also axially retained, is not rendered obvious from the prior art.

(c) In a further line of argumentation, the problem was seen in reducing the length of the device during dose setting. The skilled person would simply make the sleeve 116 shorter. This might have the effect that the not selected ciphers were not shielded - however this was also not seen as a problem for the claimed device (objection under Article 84, see point 3.7 above).

However, should the skilled person shorten the sleeve 116 such that the dial button 40 does not move axially together with the sleeve, the dose can not be ejected any more. According to D1, paragraphs [0079], [0080] and figure 29, the piston rod 94 projects the same length L out of the housing (and into the cartridge) both at a dose of zero and at any dose that can be set. The selected dose is determined by the amount of extension of the sleeve 116 out of the housing. For the ejection, the sleeve 116 and the button 40 are pushed back into the housing by the user (see paragraphs [0063, 0064]). The axially moving dose dial button is thus essential for the device of D1.

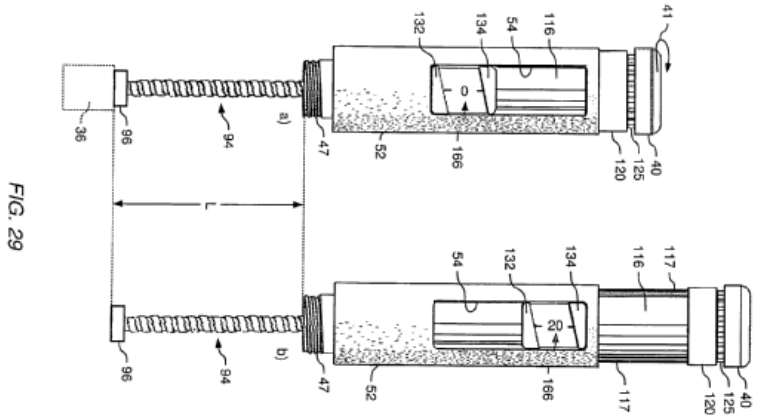


FIG. 29

4.7.4 Consequently, D1 can not render obvious the features 1.11 and 1.14a. For this reason alone, claim 1 involves

an inventive step over D1 alone. Whether claim 1, as suggested by the patent proprietor, differs from D1 in further features or not, is thus irrelevant.

4.8 D2 as closest prior art taken alone

4.8.1 The injection device of D2, figures 1 to 3 (reproduced above, see point 2.3.2), provides an automatic spring driven injection (paragraph [0024]) and discloses a housing 5a with a window, a dose dial button ("*dose setting member 1*") and a scale drum ("*indicator barrel 9*"). To set a dose the dial button is rotated thereby causing the scale drum to rotate and slide axially in sliding tracks 11 of the dose dial button (paragraphs [0025], [0026]).

4.8.2 The distinguishing features are at least 1.8 to 1.10, 1.12 (sliding element) and 1.14b (scale drum is axially retained). This is not disputed.

4.8.3 The appellant (opponent 1) argued in a first line of argumentation that claim 1 merely resulted in a foreseeable worsening of the device of D2. An axially retained scale drum would result in a much longer device compared to a device with axially movable scale drum. A predictable disadvantage however did not involve an inventive step.

In a second line of argumentation, claim 1 was a simple kinematic reversal of the concept of a movable scale drum and a fixed window of D2.

4.8.4 The Board does not agree.

First of all, the appellant (opponent 1) failed to provide a proper problem-solution approach in view of

the problem that was considered to be solved by the distinguishing features and why it was obvious to provide the features of claim 1.

Additionally, the first line of argumentation can not convince as not all distinguishing features are considered.

The second line of argumentation can likewise not convince. In a kinematic reversal of D2 (paragraph [0026]), the housing with the window would have to move and the scale drum would have to be axially retained, because the device does not have an intermediate sliding element. Furthermore, in this line of argumentation, the sliding element would still be missing.

4.9 The requirements of Article 56 EPC are thus met.

5. Description

5.1 During oral proceedings before the Board the appellant (patent proprietor) made the adapted description (as granted with adapted paragraphs [0016] and [0031] replacing the the ones of the patent specification) to the description of the main request. The adapted description was filed for the first time on 31 July 2024 in preparation for oral proceedings before the opposition division and again with the patent proprietor's reply to the opponent 1's statement of grounds of appeal.

5.2 The amended description does not need further adaptation to the claims.

5.3 To address the objection raised under Article 83 EPC concerning the releasable coupling between the dose dial button and the scale drum (see point 2.2 above), any reference to a releasable coupling in paragraphs [0016] and [0031] is deleted.

5.4 The appellant (opponent 1) argued that the adapted description would still not overcome the objection as a releasable coupling was still not excluded from claim 1. The deletion of the embodiments mentioned in the description, which fell within the scope of the claimed subject-matter, did not alter the fact that the claim still encompassed these embodiments. Claim 1 required an disclaimer according to G 0001/03 to solve the issue.

5.5 The Board does not agree.
As explained in point 2.2.2 above, embodiments with a releasable coupling between the dose dial button and the scale drum as mentioned in the patent specification as granted do not fall under claim 1 of the main request. The adapted description emphasises these findings by deleting any hint to a releasable coupling in the patent specification.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the following documents:

Claims: Claims 1 to 7 of the main request filed with

the statement of grounds of appeal of the patent proprietor.

Description: The patent specification with the amended paragraphs [0016] and [0031] filed with the patent proprietor's letter of 25 July 2025.

Drawings: of the patent specification.

The Registrar: The Chairman:

D. Grundner G. Pricolo

Decision electronically authenticated